IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE	:	
VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	:	MDL No. 2875 (RBK/KW)
	:	**MTD OPINION 5: Subsumption, Negligence, Negligence Per se, Medical Monitoring, Strict Liability of Pharmacies**
This Document Relates to All Actions.	:	

KUGLER, United States District Judge:

Before this Court are the Defendants' Motions to Dismiss (Doc. No. 520, 522, 523) the three Master Complaints filed in this Multi-District Litigation ["MDL"] that involves the sale of a generic blood pressure medication found to be contaminated with probable human carcinogens. Since the MTDs seek dismissal of several claims for each set of plaintiffs, the Court is issuing a series of opinions to resolve the motions. Each opinion will be numbered with this opinion being the fifth in the series.

This OPINION 5 resolves defendants' arguments relating to subsumption of claims by various states' Products Liability Acts, and Rule 12(b)(6) pleading deficiencies for common law claims of negligence, negligence *per se* against all three categories of defendants as well as common law claims of strict liability claims against the Pharmacy Defendants. An ORDER 5 of this date accompanies this OPINION 5.

The COURT HAVING REVIEWED the parties' submissions (without a hearing in accordance with Rule 78.1 (b)) relating to these arguments, and for the reasons stated below, and for good cause shown, the Court rules as set forth in Conclusion 7.0 *infra*.

1.0 FACTS AND PROCEDURAL BACKGROUND

The Court having presented facts underlying this MDL in the previous four MTD opinions, this review is kept short. Moreover, the Court hereby incorporates herein the facts, procedural history, and background of the other four MTD opinions, especially to the extent necessary to explicated pleaded facts in the Master Opinions that particularly relate to subsumption and negligence claims.

This MDL involves the generic active pharmaceutical ingredient, Valsartan, and the finished drugs produced with it, collectively termed here valsartan-containing drugs or VCDs. VCDs are universally prescribed drugs to lower blood pressure and/or treat heart failure.

In the summer of 2018, the U.S. Federal Drug Administration ["FDA"] and several of its counterparts in Europe and Canada discovered that certain batches of generic Valsartan[1] contained nitrosamines, known carcinogens, in amounts above what the FDA considered allowable, that is above 96 nanograms (ng) per day. The first nitrosamine contaminant found was N-nitrosodimethylamine ["NDMA"]. Within a few months, other nitrosamines, which included N-Nitrosodimethylamine ["NDEA"], were also found in batches of VCDs.

In August 2018, these governmental health administrations began recalling VCDs made with the active pharmaceutical ingredient produced by certain API Manufacturers located in China or India. These include Zhejiang Huahei Pharmaceuticals Ltd. and Aurobindo Pharmaceuticals. The contaminated API had gone into a finished pill made by Finished Manufacturers located in India and Israel, which include Teva Pharmaceuticals, Mylan Pharmaceuticals, and Torrent. Many of these Manufacturers also began issuing their own recalls of contaminated VCDs already in the drug supply chain. To be clear, almost all generic Valsartan sold in the U.S. had come from these API Manufacturers and Finished Manufacturers.

After the recalls began, FDA testing revealed the valsartan API manufactured by and for defendants had levels of NDMA of between 15,180 and 16,300 ng, much in excess of the FDA daily limit. Further, FDA testing revealed levels of NDEA was similarly well in excess of FDA limits.

VCDs were (and remain) a drug of choice in lowering high blood pressure. Since they were widely prescribed worldwide and in the United States, the recalls caused consternation during much of 2019 in the global medical community, including the American Medical Association, both as there developed a shortage of VCDs and as physicians moved their patients to some other drug perceived less effective in order to avoid potential contamination. Several months after the recalls, the FDA (and non-U.S. health administrations) posited the contaminants in the VCDs to be the result of changes the API Manufacturers had adopted in their manufacturing processes, particularly in the solvents used. Some API Manufacturers had adopted manufacturing changes as early as 2012, which means potentially contaminated API may have been present in much of the Valsartan drug supply sold in the U.S. for about 6 years.

By late August 2018, plaintiffs had begun filing personal injury individual complaints. By October 2018, individual plaintiffs and third-party payors who had paid for individual plaintiffs' prescriptions of the contaminated Valsartan, filed several class actions alleging economic losses. (Doc. No. 1). Consumers also filed a medical monitoring class action alleging "cellular damage, genetic harm, and/or an increased risk of developing cancer" as a result of exposure to the human carcinogens in the VCDs. Lastly, personal injury claims were filed on behalf of consumers who alleged they had developed cancer as a result of taking the contaminated VCDs.

[1] Valsartan is the generic name of a now off-patent drug Diovan® and is also used in a combination heart failure drug called Exforge®.

On 14 February 2019, the Judicial Panel on Multi-District Litigation ["JPML"] consolidated all of the individual filings into this MDL, No. 2875. On 17 June 2019, three Master Complaints were filed with this Court: the Economic Loss Master Complaint ["ELMC"] at ECF Doc. 121., the Personal Injury Master Complaint ["PIMC"] at ECF Doc. 122; and the Medical Monitoring Master Complaint ["MMMC"] at ECF Doc. 123. Since then, this MDL has advanced significantly, both in terms of filings and in the management of the litigation through various discovery phases. Currently, with over 700 pending filings, the MDL is well into the discovery phase of intensive document production; and, depositions of individuals and under Rule 30(b)(6) are proceeding.

1.1 ECONOMIC LOSS MASTER COMPLAINT

Plaintiffs in this Master Complaint (ECF Doc. 121) include individual consumers who purchased the VCDs at issue as well as third party payors ["TPPs"] that paid or co-paid for the VCDs at issue that consumers ingested. TPPs are health care benefit providers, such as an employer's insurance company providing health care benefit to employees. Many of the TPPs providing such health care benefits have assigned their rights to recovery in this MDL to a select few entities, termed assignors, who now stand as plaintiffs here.

Since the VCDs at issue had been FDA-approved as a generic of an FDA-approved branded drug listed in the Orange Book, plaintiffs assert generally that defendants lied to the public when the VCDs at issue were sold and identified as an approved generic. That is, the contaminants made the VCDs at issue differ substantially from the FDA-approved generic.

Plaintiffs' claims include:

- Common Law Breach of express warranties by all defendants because inclusion of defendants' VCDs in the U.S. Orange Book serves as a warranty that the VCDs at issue constituted a generic drug that is bio-equivalent in every way to the patented drug.

- State Law Breach of implied warranties and of warranty for fitness of purpose by all, or all but the Pharmacy, defendants under the law of each state, the District of Columbia, and Puerto Rico.

- Breach of the Magnuson-Moss Warranty Act under 15 U.S.C. §2301 *et seq.* by all, or all but the Pharmacy, defendants.

- Fraud, intentional misrepresentation and/or negligent misrepresentation by all, or all but the Pharmacy, defendants by omitting to inform the public the VCDs at issue were not bio-equivalent to the branded, FDA-approved drug.

- Breach of State Consumer Statues for Unfair Competition or False Advertising in all fifty states and in the District of Columbia and Puerto Rico.

- Unjust Enrichment against all, or all but Pharmacy, defendants.

- Common law negligence against all, or all but Pharmacy, defendants for breaching their duty to exercise reasonable care to oversee the safety of the VCDs at issue and prevent injury to plaintiffs and for failing to comply with current Good Manufacturing Practice ["cGMP"] federal regulations.

- Common law negligence *per se* against all, or all but Pharmacy, defendants for failing to ensure that VCDs sold in the U.S. were therapeutically equivalent to the Orange Book entry and failing to act as reasonably prudent actors throughout the U.S. drug supply chain.

1.2 PERSONAL INJURY MASTER COMPLAINT

The plaintiffs in this Master Complaint include all those who pleaded in their individual actions that they had suffered personal injuries as a result of the use of the VCDs at issue as well as, where applicable, plaintiffs' spouses, children, parents, decedents, wards, and heirs as represented by plaintiffs' counsel. The plaintiffs plead many of the same claims as in the ELMC, but do NOT exclude the Pharmacy defendants.

The claims specific to the PIMC include:

- Strict liability/product liability-manufacturing defects for making a drug that was not bio-equivalent to the Orange Book entry or to the patented drug because of flawed, faulty, and non-compliant cGMPs, which created a foreseeable and unreasonable danger to those ingesting the VCDs at issue.

- Strict liability/product liability-failure to warn, to physicians that the VCDs at issue would cause harm.

- Strict liability/product liability-design defect, that the VCDs at issue failed to perform in a safe manner expected by an ordinary consumer and increased the risk of causing cancer.

- Wrongful Death, that certain plaintiffs died as a result of the injury causes by ingesting unreasonably harmful VCDs that defendants made and marketed throughout the U.S. drug supply.

- Survival Action, that decedent plaintiffs before death were caused injury, including loss of body function, disability, pain and suffering and loss of economy, as a result of ingesting unreasonably harmful VCDs that defendants made and marketed throughout the U.S. drug supply.

- Loss of Consortium

- Punitive Damages, because defendants' actions to make and market extremely dangerous drugs constitutes fraud and malice.

Claims similar to the ELMC include:

- Common Law Negligence, that defendants breached a duty to plaintiffs and physicians to exercise ordinary care in making the VCDs at issue and that such breach caused injury.

- Common Law Negligence *per se*, defendants' actions of making and selling a contaminated drug, while also violating federal and state law, also breached a common law duty by failing to act as reasonably prudent actors throughout the U.S. drug supply chain.

- Common Law Breach of Express Warranty, that defendants, through the drug labels and packaging of the VCDs at issue, made express representations to health care professionals about their quality and to consumers that ingestion of these was safe, which representations constituted an express warranty of drug safety and purity that was false.

- Common Law Breach of Implied Warranty and Fitness of Purpose, that defendants placed the VCDs at issue in the stream of commerce, implying that they were safe and fit for their purpose.

- Common Law Fraud and Intentional Misrepresentation, that defendants knew or should have known the VCDs at issue were unreasonably dangerous and intentionally concealed that fact to health care professionals and consumers.

- Common Law Negligent Misrepresentation, that defendants made untrue representations about the safety and quality of the VCDs at issue to health care professionals and to consumers.

- Breach of Consumer Protection Statutes, that defendants engaged in unfair competition by failing to warn plaintiffs of the unreasonable danger of the VCDs at issue, thereby violating the statutes of each state, the District of Columbia, and Puerto Rico.

1.3 MEDICAL MONITORING MASTER COMPLAINT

Plaintiffs in this Master Complaint include those consumers who ingested the VCDs at issue, thereby suffering cellular damage and genetic harm, and consequently are at an increased risk of developing cancer but have not yet been so diagnosed. The plaintiffs plead many of the same claims as in the PIMC and some of the same claims as in the ELMC, but do NOT exclude the Pharmacy defendants. The claims specific to the MMMC include:

- Medical Monitoring,

- Statutory Breach of Implied Warranty of Merchantability, that defendants placed the VCDs at issue in the stream of commerce, implying that they were safe and fit for their purpose in violation of laws in all 50 states, the District of Columbia, and Puerto Rico.

- Statutory Breach of Express Warranty of Merchantability, that defendants, through the drug labels and the packaging of the VCDs at issue, made express representations to health care professionals about their quality and to consumers that ingestion of these was safe, which representations constituted an express warranty of drug safety and purity that was false and which was a violation of laws in all 50 states, the District of Columbia, and Puerto Rico.

The claim similar to that in the ELMC includes:

- Breach of the Magnuson-Moss Warranty Act under 15 U.S.C. §2301 *et seq.* by all defendants.

The claims similar to those in the ELMC and PIMC include:

- Common Law Negligence, that defendants breached a duty to plaintiffs and physicians to exercise ordinary care in making the VCDs at issue and that such breach caused injury.

- Common Law Negligence *per se*, defendants' actions of making and selling a contaminated drug, while also violating federal and state law, also breached a common law duty by failing to act as reasonably prudent actors throughout the U.S. drug supply chain.

- Strict liability/product liability-manufacturing defects for making a drug that was not bio-equivalent to the Orange Book entry or to the patented drug because of flawed, faulty, and non-compliant cGMPs, which created a foreseeable and unreasonable danger to those ingesting the VCDs at issue.

- Strict liability/product liability-failure to warn, to physicians that the VCDs at issue would cause harm.

- Common Law Breach of Implied Warranty and Fitness of Purpose, that defendants placed the VCDs at issue in the stream of commerce, implying that they were safe and fit for their purpose.

- Common Law Breach of Express Warranty, that defendants, through the drug labels and packaging of the VCDs at issue, made express representations to health care professionals about their quality and to consumers that ingestion of these was safe, which representations constituted an express warranty of drug safety and purity that was false.

- Common Law Fraud and Fraudulent Concealment, that defendants knew or should have known the VCDs at issue were unreasonably dangerous and intentionally concealed that fact to health care professionals and consumers.

1.4 DEFENDANTS

Currently, there are about 40 defendants in this MDL, divided into 3 categories as described above: Manufacturers, which include the Manufacturers of the Active Pharmaceutical Ingredient ["API Manufacturers"], such as Zhejiang Huahei Pharmaceuticals Ltd., Hetero Laboratories, Aurobindo Pharma and Mylan Laboratories;[2] and the Finished Dose Manufacturers, such as Teva Pharmaceuticals and Torrent ["Finished Manufacturers"]; Wholesalers, such as Amerisource Bergen, Cardinal Health and McKesson; and Pharmacies, such as Walgreens, Walmart, Kroger, CVS and others. Each category of defendant has filed its own motion to dismiss.

The Court recognizes that the Manufacturers MTD has set forth the four arguments of Standing, Preemption and Primary Jurisdiction, Subsumption, and Deficiencies of Specific Claims, which the

[2] This listing of defendants is not complete but exemplary.

Wholesalers and the Pharmacies have incorporated by reference into their MTDs. In addition, the Wholesalers and the Pharmacies have each argued the facial deficiency of specific claims that are particularly pertinent to their status in the drug supply chain.

2.0 MOTION TO DISMISS STANDARD

Federal Rule of Civil Procedure 12(b)(6) allows a court to dismiss an action for failure to state a claim upon which relief can be granted. When evaluating a motion to dismiss, "courts accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (quoting *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)). In other words, a complaint survives a motion to dismiss if it contains enough factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

To make this determination, courts conduct a three-part analysis. *Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010). First, the Court must "tak[e] note of the elements a plaintiff must plead to state a claim." *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 675 (2009)). Second, the Court should identify allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth." *Id.* (quoting *Iqbal*, 556 U.S. at 680). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* (quoting *Iqbal*, 556 U.S. at 678). Finally, "when there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." *Id.* (quoting *Iqbal*, 556 U.S. at 679). A complaint cannot survive a motion to dismiss where a court can only infer that a claim is merely possible rather than plausible. *Ibid.*

3.0 SUBSUMPTION

3.1 New Jersey

Manufacturer Defendants argue that many of plaintiffs' state common law claims are subsumed under the New Jersey Product Liability Act ("NJPLA") and other similar state product liability acts.[3] ECF Doc. 520: 46. Specifically, defendants assert that all claims, except for the breach of express warranty claims, are subsumed because the NJPLA provides the sole basis for relief in products liability cases. *Ibid.* The Wholesaler and the Pharmacy Defendants incorporate these subsumption arguments by reference in their motions to dismiss. Therefore, before addressing the sufficiency of Plaintiffs' pleadings, the Court considers whether the NJPLA subsumes plaintiffs' common law claims.

[3] Wholesaler and Pharmacy Defendants likewise incorporate this argument.

The NJPLA allows a plaintiff to recover damages against the manufacturer or seller of a product upon proof "that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose." N.J.S.A. 2A:59C-2. A product liability action is a claim for harm caused by a manufacturing, warning, or design defect, "except actions for harm caused by breach of an express warranty[.]" N.J.S.A. 2A:58C-1(b)(3). A plaintiff may recover damages under the NJPLA for the following "harm" caused by a product: (1) physical damage to property; (2) personal physical illness, injury, or death; (3) pain and suffering, mental anguish, or emotional harm; and (4) any loss of consortium or services.

This Court has held that, in implementing the NJPLA "the Legislature intended 'to limit the expansion of products-liability law' and 'to limit the liability of manufacturers so as to balance[] the interests of the public and the individual with a view towards economic reality.'" *Hindermyer v. B. Braun Med. Inc.*, 419 F. Supp. 3d 908, 817 (D.N.J. 2019) [*quoting Zaza v. Marquess & Nell, Inc.*, 675 A.2d 620 (1996)). As such, the NJPLA is "both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products." *In re Lead Paint Litigation*, 924 A.2d 484, 436–37 (N.J. 2007) [*citing* N.J.S.A. § 2A:58C-1(b)(3) (defining "product liability action")]. Consequently, as the Third Circuit has explained, the NJPLA "effectively creates an exclusive statutory cause of action for claims falling within its purview." *Repola v. Morbark Indus., Inc.*, 934 F.2d 483, 492 (3d Cir. 1991). In short, these former common-law causes of action (with the exception of breach of express warranty) have merged into a single cause of action under the NJPLA. *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 596 (D.N.J. 2015).

In line with this reasoning, New Jersey federal and state courts, as well as the Third Circuit, have consistently dismissed product-liability-related claims based on common law theories when at the heart of those theories is the potential "harm caused by a product." *See, e.g.*, *Port Auth. of N.Y. & N.J. v. Arcadian Corp.*, 189 F.3d 305, 313 (3d Cir. 1999) [*dismissing* negligence claim, because "under New Jersey law negligence is no longer viable as a separate claim for harm caused by a product"]; *Thomas v. Ford Motor Co.*, 70 F. Supp. 2d 521, 528–29 (D.N.J. 1999) [*dismissing* common-law claim for negligent manufacture]; *Reiff v. Convergent Techs.*, 957 F. Supp. 573, 583 (D.N.J. 1997) [*dismissing* negligence and implied breach of warranty claims]; *McWilliams v. Yamaha Motor Corp. USA*, 780 F. Supp. 251, 262 (D.N.J. 1991) [*dismissing* negligence and breach of implied warranty claims], *aff'd in part, rev'd in part on other grounds*, 987 F.2d 200 (3d Cir. 1993); *Green v. GMC*, 709 A.2d 205 (N.J. Super. Ct. App. Div. 1998) [*stating* that "causes of action for negligence, strict liability[,] and implied warranty have been consolidated into a single product liability cause of action" under the NJPLA].

Courts have also historically dismissed common law and statutory fraud claims when the harm alleged was caused by a product. *See Brown v. Philip Morris, Inc.*, 228 F. Supp. 2d 506, 517 (D.N.J. 2002) [*preempting* fraud claim NJPLA when defendant's alleged misrepresentations resulted in "harm caused by a product."]; *Sinclair v. Merck & Co.*, 948 A.2d 587 (2008) [*subsuming* statutory consumer fraud claim by

the NJPLA when the "[t]he heart of plaintiff's case [was] the potential harm caused by Merck's drug];*McDarby v. Merck & Co.*, 949 A.2d 223 (N.J. Super. Ct. App. Div. 2008) [*subsuming* statutory consumer fraud claim by the NJPLA because "the gravamen of [the] claim was that Merck marketed Vioxx fully aware of its cardiovascular risk [and] made misrepresentations[] and . . . omis[sions]" in connection with its marketing]; *Lopienski v. Centocor, Inc.*, No. 07-4519, 2008 WL 2565065, at *1 n.2 (D.N.J. 25 Jun. 2008) [*finding* causes of action for negligence, breach of implied warranty, negligent and fraudulent misrepresentation, statutory consumer fraud, and fraudulent concealment were subsumed because they were premised on physical injuries caused by a product].

Recently, in *Sun Chemical Corp. v. Fike Corp.,* 235 A.3d 145 (N.J. 2020), the New Jersey Supreme Court's clarified the scope of subsumption under the NJPLA by addressing whether that Act subsumed claims for relief under the New Jersey Consumer Fraud Act. *Ibid.* There, the court resolved whether "a Consumer Fraud Act claim [can] be based, in part or exclusively, on a claim that also might be actionable under the Products Liability Act." *Id.* at 148. The *Sun Chemical* plaintiff bought defendant's product to prevent potential explosions in its dust collection system. *Id.* at 149. When selling the product, the defendant made several affirmative misrepresentations, namely, that the product would in fact prevent explosions. *Ibid.* The product later malfunctioned, exploded, and caused personal injury and property damage. *Ibid.*

The *Sun Chemical* court noted: "[i]t is the nature of the claims brought, and not the nature of the damages sought, that is dispositive of whether the PLA precludes the separate causes of action" (*Id.* at 148) and held: "[i]f a claim is premised upon a product's manufacturing, warning, or design defect, that claim must be brought under the PLA with damages limited to those available under that statute" , thereby precluding the CFA claims. *Id.* at 155. But, the *Sun Chemical* court notably clarified that "nothing about the PLA prohibits a claimant from seeking relief under the CFA for deceptive, fraudulent, misleading, and other unconscionable commercial practices in the sale of the product." *Ibid.* Therefore, "if a **claim is based on deceptive, fraudulent, misleading, and other unconscionable commercial practices, it is not covered by the PLA** and may be brought as a separate CFA claim." *Ibid.*, [emphasis added].

Importantly, then, the *Sun Chemical* court also held "PLA and CFA claims may proceed in separate counts of the same suit," so long as they "alleg[e] different theories of liability and seek[] dissimilar damages." *Ibid.* The *Sun Chemical* court instructed that, to determine whether the purported claim pleads a separate count, a court must "determine whether the theory pled on the facts presented, although denoted [as a CFA claim] [i]s in fact one of the three codified theories made exclusively actionable under the PLA." If so, then the claim is "supplanted by the PLA" because "claims that sound in the type of products liability action defined in the PLA must be brought under the PLA." *Ibid.*

Therefore, heeding the *Sun Chemical* instruction, the Court addresses each Master Complaint in turn to determine whether the NJPLA subsumes any of plaintiffs' claims in the Master Complaints. The claims in each Master Complaint is reviewed in turn.

3.1.1 PIMC: Subsumption of Common Law Tort Claims, Common Law Fraud Claims , including Negligent Misrepresentation, and Statutory Consumer Protection Law Claims (Styled as Fraud)

The PIMC pleads the following causes of action: (1) strict liability for a manufacturing defect; (2) strict liability for failure to warn; (3) strict liability for a design defect; (4) negligence; (5) negligence *per se*; (6) breach of express warranty; (7) breach of implied warranty; (8) fraud; (9) negligent misrepresentation; (14) punitive damages. As discussed above, "what kind of 'harm' a defective product causes is dispositive of whether the NJPLA governs claims brought for that harm." *Kuzian v. Electrolux Home Prods., Inc.*, 937 F. Supp. 2d 599, 607–08 (D.N.J. 2013). Thus, the Court focuses its analysis on the type of harm Plaintiffs allege in the PIMC.[4]

The PIMC alleges plaintiffs developed "cancers as a result of taking an adulterated, misbranded, and unapproved medication designed, manufactured, marketed, distributed, packaged, and sold by Defendants." PIMC (ECF Doc.122) ¶2. As such, the majority of plaintiffs' causes of action seek compensation for "injuries and/or death resulting from use of defective prescription VCDs". PIMC ¶6. The claims for strict liability for a manufacturing defect, strict liability for failure to warn, strict liability for a design defect, negligence, negligence *per se*, breach of implied warranty, loss of consortium, survival, wrongful death, and punitive damages seek compensation for such harm. *See, e.g.*,:

-PIMC ¶437 *seeking* to recover under strict liability cause of action for "serious injuries" due to "manufacturing defects";

- PIMC ¶449 *seeking* to recover under strict liability failure to warn cause of action for "serious injuries of a personal and pecuniary nature" due to "adulterated drug[s]";

- PIMC ¶455 *seeking* to recover under strict liability design defect cause of action because the "drugs were designed in a way that caused consumers to suffer injuries, including but not limited to cancer[.]");

- PIMC ¶464 *seekin*g to recover under negligence cause of action because Plaintiffs "use[d] their products to the detriment of Plaintiffs' health, safety, and well-being");

- PIMC ¶476 *seeking* to recover under negligence *per se* cause of action because Plaintiffs consumed "an unreasonably dangerous product proximately causing injuries";;

[4] As an initial matter, the Court notes that the NJPLA specifically allows Plaintiffs to simultaneously bring breach of express warranty claims. Such claims are not subsumed by the NJPLA. *See Clements*, 111 F. Supp. 3d at 596.

- PIMC ¶496 *seeking* to recover for breach of implied warranty after "Plaintiff[s] ingested these unapproved and unreasonably dangerous valsartan-containing drugs and suffered severe and debilitating injuries";

- PIMC ¶581 *seeking* to recover for wrongful death because the "valsartan-containing drugs they designed, manufactured, labeled, marketed, packaged, distributed, and/or sold" caused Plaintiffs' deaths;

PIMC ¶¶588–592 *pleading* similar allegations for the survival claim;

- PIMC ¶¶593–600 *pleading* similar allegations for loss of consortium claims.

Thus, these allegations in the PIMC establish plaintiffs are seeking to recover for harm caused by a product.

Because of that, the Court finds the NJPLA subsumes the common law claims in the PIMC for strict liability for a manufacturing defect, strict liability for failure to warn, strict liability for a design defect, negligence, negligence *per se*, breach of implied warranty, loss of consortium, survival, wrongful death, and punitive damages.

The fraud and negligent misrepresentation claims present a closer case. The PIMC seeks to recover under a theory of fraud because "Defendants intended to cause Plaintiffs and Plaintiffs' physicians to rely on their concealment of information and/or misrepresentations about the safety risk related to these drugs to induce them to prescribe and ingest the drugs." PIMC ¶507. Plaintiffs allege that they did in fact rely on Defendants' concealment of information about the safety risks related to the VCDs and ingested these drugs. *Id*. ¶508. As a result, "Plaintiffs were injured and incurred damages, including but not limited to medical and hospital expenses, lost wages and lost earning capacity, physical and mental pain and suffering, and loss of the enjoyment of life." *Id*. ¶509. The negligent misrepresentation claim includes similar allegations and seeks to recover for similar harm. *See Id*. ¶¶516–18.) While this is a closer call, the Court finds that plaintiffs still seek to recover for harm caused by a product. At its core, the fraud and negligent misrepresentation causes of action concern physical injuries suffered as a result of the VCDs. As such, these claims still fall within the purview of the NJPLA, and therefore also subsumed.

The last claim to analyze is the claim of violation of state consumer protection statutes, which also presents a closer call and over which the Court, still relying on *Sun Chemical* , finds the NJPLA subsumes. As discussed above, the N.J. Supreme Court held that so long as each of the NJ PLA claims and the NJ CFA claims "alleg[e] different theories of liability and seek[] dissimilar damages," the CFA claim *could* proceed in the same action. *Sun Chemical Corp. v. Fike Corp.*, 235 A.3d at 155. But, that is not the case here, where the NJ PLA claims and the CFA claims are nearly indistinguishable. For example, the CFA claim seeks virtually the same damages as the claim for breach of implied warranty and other claims

subsumed by the NJPLA.[5] Nor does the CFA claim plead any additional facts to support a different theory of liability. The claim for violation of the CFA is but another attempt to recover for personal injuries caused by the VCDs and the Court finds that the NJPLA subsumes the claim of violation of consumer protection statutes CFA claim .

[5] *Compare* PIMC ¶579 *seeking* "compensatory and punitive damages" because Plaintiffs "suffer[ed] personal injury, economic loss, pecuniary loss, loss of companionship and society, mental anguish[,] and other compensable injuries.") *with* PIMC ¶496 *seeking* damages for "severe and debilitating injuries, economic loss, and other damages, including but not limited to, cancer, cost of medical care, rehabilitation, lost income, cancer, pain and suffering and great emotional and mental distress and anguish".

3.1.2 MMMC: Subsumption of Common Law Tort Claims, Common Law Fraud Claims , including Negligent Misrepresentation, and Statutory Consumer Protection Law Claims (Styled as Fraud)

The Court next considers the MMMC, ECF Doc. 123.. The crux of the MMMC is that Plaintiffs "consumed Defendants' generic [VCDs] that were contaminated," and thus Plaintiffs "suffered cellular damage, genetic harm, and/or are at an increased risk of developing cancer as a result[.]" (MMMC ¶1.) The MMMC pleads the following causes of action: (1) negligence; (2) negligence *per se*; (3) medical monitoring; (4) products liability–manufacturing defect; (5) failure to warn; (6) violation of the Magnuson-Moss Warranty Act; (7) breach of the implied warranty of merchantability; (8) breach of express warranties; and (9) fraud/fraudulent concealment.

As with the PIMC, many of the claims pleaded in the MMMC seek to recover for harm—and potential future harm—caused by the VCDs. *See, e.g.*,

MMMC ¶404, for negligence claim, *alleging* harm of "cellular and genetic injury that creates and/or increases the risk that Plaintiffs will develop cancer";

MMMC ¶41, for negligence *per se* claim *pleading* similarly as for negligence claims;

MMMC ¶424 *seeking* to recover under medical monitoring claim for "cancer, or an increased risk of developing cancer" caused by VCDs;

MMMC ¶464 *seeking* to recover under implied warranty claim because Plaintiffs "have been injured and suffered damages, in that Defendants' VCDs they consumed were contaminated . . . and thus created and/or increased the risk that Plaintiff and other Class members will develop cancer.");

MMMC ¶490 *seeking* to recover under fraud claim because "Defendants VCDs [Plaintiffs] consumed were contaminated . . . and thus created and/or increased the risk that Plaintiff and other Class members will develop cancer."

For those same reasons articulated above, the Court finds that the NJPLA subsumes plaintiffs' claims in the MMMC for negligence, negligence *per se*, medical monitoring, strict liability-manufacturing defect, strict liability-failure to warn, strict liability-design defect, breach of implied warranty, and fraud. The claim for breach of express warranty remains.[6]

Accordingly, the Court **GRANTS WITH PREJUDICE** the motion of the Manufacturer Defendants and the incorporated-by- reference motions of the Wholesaler Defendants and the Pharmacy Defendants to dismiss the common law claims in either or both the PIMC and MMMC for strict liability (all variants)[7], negligence, negligence *per se*, breach of implied warranty, fraud, negligent

[6] As the Court has previously dismissed the claim for Violation of the Magnuson-Moss Warranty Act, the Court does not address this claim under the subsumption analysis.

[7] Strict liability variants include strict liability-manufacturing defect, strict liability-design defect, strict liability-failure to warn.

misrepresentation, wrongful death, survival, loss of consortium, and punitive damages, as well as the claim for violation of the statutory consumer protection law, which arise under New Jersey law.

Accordingly, since the NJPLA expressly exempts claims for breach of express warranty, the Court **DENIES** the Manufacturer Defendants' motion to dismiss those claims for breach of express warranty arising under New Jersey law. This denial accords with the Court's previous motion to dismiss claims in its MTD Opinion 3, ECF Doc. 775:3, 15; and in its MTD Order 3, ECF Doc. 776: 1.

Moreover, the Court previously **GRANTED** the Wholesaler Defendants' and the Pharmacy Defendants' motions to dismiss claims for breach of express warranty for the reasons stated in its MTD Opinion 3, ECF Doc. 775: 16-17, and had given plaintiffs a thirty-day period from the date of MTD Opinion 3 in which to file a motion for leave to amend their complaints.

3.1.3 ELMC: NJPLA Subsumption of Common Law Tort Claims, including negligence and negligence per se, Unjust Enrichment Claims, Common Law Warranty Claims, Common Law Fraud Claims , including Negligent Misrepresentation, and Statutory Consumer Protection Law Claims (Styled as Fraud)

The ELMC asserts the following causes of action: (1) breach of express warranty; (2) breach of implied warranty of merchantability and fitness; (3) violation of the Magnuson-Moss Warranty Act; (4) fraud; (5) negligent misrepresentation; (6) violation of state consumer protection laws; (7) unjust enrichment; (8) negligence; and (9) negligence *per se*. While the PIMC and the MMMC seek to recover for harm caused by a product, the ELMC seeks to recover for a distinct harm. The ELMC brings a claim for "economic damages . . . on behalf of VCD consumers and third-party payors who paid or made reimbursements for Defendants' adulterated, misbranded, and/or unapproved VCDs illegally manufactured, sold, labeled, marketed, and distributed in the United States". ELMC ¶4.

`This Court has repeatedly held that "claims alleging that a plaintiff 'did not get what [they] paid for' are not subsumed by the PLA." *Gorczynski v. Electrolux Home Prods., Inc.*, No. 18-10661, 2019 WL 5304085, at *3 (D.N.J. Oct. 18, 2019) (citing *Volin v. Gen. Elec. Co.*, 189 F. Supp. 3d 411, 418 (D.N.J. 2016) (denying motion to dismiss where plaintiff alleged that she did not get what she paid for when she purchased defective product)). The key inquiry to determine whether such a claim is subsumed is whether the plaintiff is "seek[ing] any damages for, physical harm caused by the [defect]." *Ibid.* Additionally, the Third Circuit explains, where the New Jersey PLA does not cover the type of damages alleged, the "PLA cannot subsume that which it explicitly excludes from its coverage." *Estate of Edward W. Knoster v. Ford Motor Co.*, 200 F. App'x 106, 116 (3d Cir. 2006) [*finding* there was no overlap between the CFA where plaintiffs sought only economic damages resulting from the harm to the product itself].

For example, in *Montich v. Miele USA, Inc.*, 849 F. Supp. 2d 439, 456 (D.N.J. 2012), a plaintiff purchased from defendant a washing machine that later malfunctioned and brought claims against the manufacturer for breach of implied warranty, violation of consumer protection statutes, and unjust enrichment. *Ibid.* The manufacturer argued the claims were subsumed by the New Jersey PLA because the plaintiff's harm was caused by the washing machine but the Court disagreed. The plaintiff's allegations established that "she paid a substantial sum for a washing machine she can no longer use," and therefore the court found the damages "flow[ed] from the price she paid . . . and the fact that she cannot now use her washing machine for its particular purpose". *Id.* at 456-457. Concluding the harm was not "caused by the washing machine"; but was "the malfunction of the washing machine itself, the Court found the claims were not subsumed. *Id.* at 457-458.

Similarly, here, the harm pleaded in the ELMC was not caused by the VCDs, but by the malfunctioning of the VCDs. The ELMC pleads that plaintiffs paid a substantial sum for what they assumed were generic, **uncontaminated** VCDs. However, the VCDs "were not fit for their ordinary use". ELMC ¶10. The alleged harm for each cause of action in the ELMC emanates from the unfit condition of the VCDs to be ingested as generic drugs. *See, e.g.*,

ELMC ¶445, for breach of warranty claim *alleging*. harm of "damages in the amount of the purchase price of their medications, the purchase price of any replacement medications, and any consequential damages . . . in that the VCDs they purchased were so inherently flawed, unfit, or unmerchantable as to have no market value".;

ELMC ¶463 *pleading* similar allegations for breach of implied warranty claim;

ELMC ¶495, for fraud claim, *pleading* harm of being "fraudulently induc[ed] . . . to pay in whole or in part for Defendants' VCDs—products which Defendants knew or should have known were not therapeutically equivalent to their RLDs and/or did not comply with GMP";

ELMC ¶¶ 527, 529, for negligent misrepresentation claim, *alleging* plaintiffs "were damaged by reason of each Defendant's misrepresentation" and but for "these misrepresentation (or omissions) Plaintiffs and other Class Members would not have made purchases of Defendants' VCDs.";

ELMC ¶548 *pleading* similar allegations for breach of consumer protection statutes ;

ELMC ¶559, for unjust enrichment claim, pleading plaintiffs "were unjustly deprived of money obtained by Defendants as a result of the improper amounts paid for Defendants' VCDs."); *i*

ELMC ¶573, in support of negligence claim, pleading defendants "were obligated to ensure that its VCDs complied with cGMPS and were not adulterated or misbranded" and the failure to do so ended in "damage [to] Plaintiffs and the Class [to] increase [Defendants'] profits".

Based on these allegations in the ELMC, Court finds plaintiffs do not seek to recover for damage caused by a product and for that reason, that the NJPLA does not subsume the ELMC claims.

Accordingly, the Court **DENIES** the motion of the Manufacturer Defendants and the incorporated-by- reference motions of the Wholesaler Defendants and Pharmacy Defendants to dismiss those common law claims in the ELMC for breach of express warranty, breach of implied warranty of merchantability and fitness, fraud; negligent misrepresentation, unjust enrichment, negligence, and negligence *per se* as well as claims for violation of state consumer protection laws, and violation of the Magnuson-Moss Warranty Act[8], which arise under New Jersey law.

The Court's Opinion 3 expresses its detailed rulings on the Breach of Implied and Express Warranty Claims with which this Opinion5 corresponds.

The Court's Opinion 3 expresses its detailed rulings on the Breach of Implied and Express Warranty Claims with which this Subsumption Opinion5 corresponds.

3.2 OTHER STATE LAW

Defendants also contend that plaintiffs' claims should be dismissed under the subsumption laws of nine other jurisdictions, each of which the Court addresses in turn.

3.2.1 CONNECTICUT

3.2.1.1 PIMC and MMMC

Defendants assert that the Connecticut Product Liability Act ["CNPLA"] , Conn. Gen. Stat. §§ 52-572m, *et seq.*, subsumes each of plaintiffs' product liability claims. Under the CNPLA, a product liability claim includes "all claims or actions brought for personal injury, death[,] or property damage caused by the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging[,] or labeling of any product." *Id.* § 52-572m(b). This includes all actions based "on the following theories: [s]trict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation or nondisclosure, whether negligent or innocent." *Ibid.* Further, "[a] product liability claim . . . may be asserted and shall be in lieu of all other claims against product sellers, including actions of negligence, strict liability and warranty, for harm caused by a product." *Id.*. § 52-572n(a). While "[t]he statute does not abolish common law claims in product liability actions," it mandates that these claims must be "incorporate[d] . . . into a single count to simplify pleadings." *Collazo v. Nutribullet*, No. 20-575, 2020 WL 4194616, at *2 (D. Conn. 21 July 2020). Moreover, the Connecticut Supreme Court has held that the CNPLA provides the exclusive remedy for a claim falling within its scope. *Winslow v. Lewis-Shepard, Inc.*, 562 A.2d 517, 517 (Conn. 1989).

[8] *See supra* fn. 6.

Since the following claims in the PIMC and the MMMC arise out of personal injury, or prospective future personal injury, caused by a product, the Court finds the CNPLA subsumes them:

the PIMC claims for strict liability- manufacturing defect; -design defect; -failure to war, negligence, negligence *per se*, breach of express warranty, breach of implied warranty, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages and to

the MMMC claims for negligence, negligence *per se*, medical monitoring, strict liability-manufacturing defect, strict liability-failure to warn, breach of implied warranty, breach of express warranty, and fraud. *See Collazo*, 2020 WL 4194616 at *2. To be clear, these specific claims are by no means prohibited, but the CNPLA requires they be brought as incorporated into a single cause of action within these Complaints.

Moreover, as for the PIMC claim for violation of state consumer protection statutes, the Connecticut Supreme Court has recognized that such a claim "may be asserted in conjunction with the product liability act claim." *Gerrity v. R.J. Reynolds Tobacco Co.*, 818 A.2d 769, 775 (Conn. 2003). However, such a claim may only be asserted if it does not seek "a remedy for personal injury, death, or property damages." *Id.* Rather, a claim for violation of the consumer protection statute must seek "merely a *financial injury* suffered by the decedent, of a kind that has never been regarded as part of the traditional tort remedy for harm caused by a defective product." *Id.* (emphasis in original). Here, the PIMC does not seek to recover under this cause of action for any separate damages. Rather, the claim seeks damages for personal injury. Therefore, the Court finds the CNPLA also subsumes claims for violation of state consumer protection statutes.

Accordingly, the Court **GRANTS WITH PREJUDICE** the motion of the Manufacturer Defendants and the incorporated-by- reference motions of the Wholesaler Defendants and Pharmacy Defendants to dismiss: 1) in the PIMC those common law claims for strict liability (all variants), negligence, negligence *per se*, breach of express warranty, breach of implied warranty, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages as well as that claim for violation of the state consumer protection laws; and

2) in the MMMC those common law claims for negligence, negligence *per se*, medical monitoring, strict liability (all variants), breach of implied warranty, breach of express warranty, and fraud, which arise under Connecticut law.

3.2.1.2 ELMC

As to the ELMC, the Connecticut PLA specifies that "commercial loss caused by a product is not harm and may not be recovered by a commercial claimant in a product liability claim." Conn. Gen. Stat. Ann. § 52-572n(c). As such, courts interpreting Connecticut law have held that "[w]here a

manufacturer wrongfully induces a consumer to pay a higher price for a given product with a representation that, in exchange for the higher price, the consumer is gaining a particular, added benefit, a claim seeking relief for the financial injury resulting from the manufacturer's misrepresentation is outside the scope of the" Connecticut PLA. *Morris v. Viking Pools Ne., Inc.*, 492 F. Supp. 2d 90, 95 (D. Conn. 2007). In line with this reasoning, the Court finds the CNPLA does not subsume the claims in the ELMC because these relate not to harm caused by a product but arise from plaintiffs' asserted economic injuries. See *Gerrity*, 818 A.2d at 776

Accordingly, the Court **DENIES** the motion of the Manufacturer Defendants and the incorporated-by- reference motions of the Wholesaler Defendants and Pharmacy Defendants to dismiss those common law claims in the ELMC for breach of express warranty, breach of implied warranty of merchantability and fitness, fraud; negligent misrepresentation, unjust enrichment, negligence, and negligence *per se* as well as claims for violation of state consumer protection laws, which arise under Connecticut law.

..

3.2.2 INDIANA

Defendants assert the Indiana Products Liability Act ["INPLA"] subsumes all causes of action in the three Master Complaints. The INPLA "governs all actions" brought by a user or consumer "against a manufacturer or seller" for "physical harm caused by a product; regardless of the substantive legal theory upon which the action is brought" (Ind. Code § 34-20-1-1) and thus provides a "single cause of action when a consumer seeks to recover from a manufacturer or seller for physical harm." *Cincinnati Ins. Cos. v. Hamilton Beach/Proctor-Silex, Inc.*, No. 4:05 CV 49, 2006 WL 299064, at *2 (N.D. Ind. Feb. 7, 2006).

3.2.2.1 INDIANA PIMC and MMMC

As for the PIMC claims of strict liability claims, negligence, negligence *per se*, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages, which arise under Indiana law, the Court finds the INPLA subsumes them. However, the INPLA has been found to subsume neither claims of violation of state consumer protection statutes nor claims of breach of express warranty or implied warranty. *See, e.g.*, *Fowler v. Wenrer Co.*, 2014 WL 2605341, at *1 (N.D. Ind. 10 June 2014) [*holding* "the Consumer Protection Act is a separate and distinct cause of action from a Product Liability Act cause of action" *and* "a UCC breach of warranty cause of action is a separate and distinct cause of action from Product Liability cause of action "]. Therefore, the Court finds that the PIMC claims of violation of state consumer protection statutes, of breach of express warranty or of implied warranty arising under Indiana law survive the motions to dismiss.

As for the MMMC claims negligence, negligence *per se*, medical monitoring, manufacturing defect, failure to warn, and fraud, which arise under Indiana law, the Court finds the INPLA likewise subsumes them for seeking to recover for physical harm caused by the VCDs. And, again, the Court finds the MMMC claims for breach of implied warranty and breach of express warranty survive the motions to dismiss.

Accordingly, the Court **GRANTS WITH PREJUDICE** the motion of the Manufacturer Defendants and the incorporated-by- reference motions of the Wholesaler Defendants and Pharmacy Defendants to dismiss:

1)in the PIMC those common law claims for strict liability (all variants),, negligence, negligence *per se*, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages, and

2)in the MMMC those common law claims for strict liability-manufacturing defect, strict liability-design defect, strict liability-failure to warn, negligence, negligence *per se*, medical monitoring, and fraud,

which arise under Indiana law.

3.2.2.2 INDIANA ELMC

As for the ELMC claims, the Indiana Supreme Court has allowed plaintiffs in similar cases to assert both tort-based causes of action under the INPLA as well as contract-based claims under the Uniform Commercial Code. *Gunkel v. Renovations, Inc.*, 822 N.E.2d 150, 153 (Ind. 2005). The Court noted these two kinds of claims arise under distinct legal theories, finding claims under the INPLA are for "damages for a defective product or service . . . [that] cause[] personal injury", whereas contract law applies to claims for "damage to the product or service itself and purely economic loss arising from the failure of the product or service to perform as expected." *Ibid; see also Jarrett v. Wright Med. Tech., Inc.*, No. 12-00064, 2019 WL 2567708, at *3 (S.D. Ind. 21 June 2019). This finding means the INPLA does not subsume contract-based claims under the Uniform Commercial Code based on a theory that a product failed to perform as expected. *Gunkel* 822 N.E. 2d at 153. Since the ELMC claims arise out of the economic loss resulting from the failure of the VCDs to perform as expected, this Court therefore finds the INPLA does not subsume them.

Accordingly, the Court **DENIES** the motion of the Manufacturer Defendants and the incorporated-by-reference motions of the Wholesaler Defendants and Pharmacy Defendants to dismiss: in the ELMC those law claims for breach of express warranty and breach of implied warranty well as claims for violation of state consumer protection laws, which arise under Indiana law.

3.2.3 *KANSAS:* PIMC, MMMC, and ELMC

Defendants assert the Kansas Product Liability Act ["KSPLA"], Kansas Stat. Ann. 60-3301 *et seq*. subsumes many of plaintiffs' claims. The Kansas Supreme Court has stated that the KSPLA aims "to consolidate all product liability actions, regardless of theory into one theory of legal liability." *Patton v. Hutchinson Wil-Rich Mfg. Co.*, 861 P.2d 1299, 1311 (Kan. 1993). The term "product liability claim" includes "any claim or action brought for harm caused by the manufacture, production, making, construction, fabrication, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging, storage or labeling of the relevant product." Kansas Stat. Ann. 60-3302(c). And specifically, under the KSPLA, a product liability claims includes "any action based on, strict liability in tort, negligence, breach of express or implied warranty, breach of, or failure to, discharge a duty to warn or instruct, whether negligent or innocent, misrepresentation, concealment or nondisclosure, whether negligent or innocent, or under any other substantive legal theory." *Ibid.* The term "harm" includes (1) damage to property; (2) personal physical injuries, illness, and death; and (3) mental anguish or emotional harm attendant to such physical injuries, illness, or death. Kansas Stat. Ann. 60-3302(d). And, the Kansas Supreme Court has held that "all legal theories of recovery, *e.g.*, negligence, strict liability, and failure to warn, are to be merged into one theory called a 'product liability claim.'"

Consequently, for those PIMC claims of strict liability (all variants), negligence, negligence *per se*, breach of express warranty, breach of implied warranty, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages, which arise under Kansas law, and for those MMMC claims of negligence, negligence *per se*, medical monitoring, manufacturing defect, failure to warn, breach of implied warranty, breach of express warranty, and fraud, which arise under Kansas law, the Court finds the KSPLA subsumes them.

To be clear, the term "harm" does not include direct or consequential economic loss under Kansas Stat. Ann. 60-3302(d), which the Kansas Supreme Court has expressed rule on. "Because the Kansas PLA excludes from the scope of a product liability cause of action any claim to recover direct or consequential economic loss, the K[S] PLA does not subsume or extinguish any legally viable alternative cause of action seeking recovery for direct or consequential economic loss." *Patton*, 861 P.2d at 1311. This Court therefore finds the KSPLA does not subsume the claims in the ELMC.

Accordingly, the Court **GRANTS WITH PREJUDICE** the motion of the Manufacturer Defendants and the incorporated-by- reference motions of the Wholesaler Defendants and Pharmacy Defendants to dismiss

1)in the PIMC those common law claims for strict liability (all variants), negligence, negligence *per se*, breach of express warranty, breach of implied warranty, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages, and

2) in the MMMC those common law claims for negligence, negligence *per se*, medical monitoring, manufacturing defect, failure to warn, breach of implied warranty, breach of express warranty, and fraud, which arise under Kansas law.

Accordingly, the Court **DENIES** the motion of the Manufacturer Defendants and the incorporated-by-reference motions of the Wholesaler Defendants and Pharmacy Defendants to dismiss In the ELMC those common law claims for breach of express warranty, breach of implied warranty of merchantability and fitness, fraud; negligent misrepresentation, unjust enrichment, negligence, and negligence *per se* as well as claims for violation of state consumer protection laws, which arise under Kansas law.

3.2.4 *LOUISIANA*: PIMC, MMMC, and ELMC

Defendants assert the Louisiana Product Liability Act ["LAPLA"] La. Rev. Stat. Ann. § 9:2800.51 *et seq.* subsumes all common law claims, which plaintiffs do not dispute. The LAPLA "establishes the exclusive theories of liability for manufacturers for damage caused by their products." La. Rev. Stat. Ann. § 9:2800.52. Courts interpreting the LAPLA have held "drafters of the L[A]PLA sought to strictly delimit possible bases of liability for manufacturers" such that "[a] plaintiff may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability not set forth in the L[A]PLA." *Stroderd v. Yamaha Motor Corp., U.S.A.*, No. 04-3040, 2005 WL 2037419, at *2 (E.D. La. Aug. 4, 2005) [*citing Jefferson v. Lead Industries Ass'n, Inc.*, 930 F. Supp. 241 (E.D. La. 1996)). The LAPLA defines "damage" as "damage to the product itself and economic loss arising from a deficiency in or loss of use of the product only in so far as [a redhibition cause of action] does not allow recovery for such damage or economic loss." La. Rev. Stat. Ann. § 9:2800.53(5).

Based on this standard, the Court finds the LAPLA subsumes:

the PIMC claims of strict liability (all variants), negligence, negligence *per se*, breach of express warranty, breach of implied warranty, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages; and

the MMMC claims of negligence, negligence *per se*, medical monitoring, manufacturing defect, failure to warn, breach of implied warranty, breach of express warranty, and fraud; and

the ELMC claims of breach of express warranty, breach of implied warranty, fraud, negligent misrepresentation, unjust enrichment, negligence, and negligence *per se.*

Accordingly, the Court **GRANTS WITH PREJUDICE** the motion of Manufacturer Defendants motion and the incorporated-by-reference motions of the Wholesaler Defendants and the Pharmacy Defendants for those PIMC common law claims of strict liability (all variants), negligence, negligence *per*

se, breach of express warranty, breach of implied warranty, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages;

those MMMC common law claims of negligence, negligence *per se*, medical monitoring, strict liability (all variants), breach of implied warranty, breach of express warranty, and fraud; and

those ELMC common law claims of breach of express warranty, breach of implied warranty, fraud, negligent misrepresentation, unjust enrichment, negligence, and negligence *per se*,

which arise under Louisiana law.

3.2.5 *MISSISSIPPI:* PIMC, MMMC, and ELMC

Although defendants assert the Mississippi Product Liability Act ["MSPLA"], Miss. Code Ann. § 11–1–63, subsume many of plaintiffs' claims, they do not contend plaintiffs' fraud claims are subsumed. The MSPLA governs actions for damages caused by a product, including any action "based on a theory of strict liability in tort, negligence or breach of implied warranty, except for commercial damage to the product itself[.]". Courts interpreting Mississippi law have found that the Mississippi Legislature signaled its "intent for all claims brought for damage caused by a product to be analyzed under the MPLA." *Estes v. Lanx, Inc.*, No. 14-052, 2015 WL 9462964, at *5 (N.D. Miss. 23 Dec. 2015) (internal citation omitted). However, that the MSPLA provides the exclusive remedy for suits against a manufacturer does not mean that common law negligence or breach of implied warranty claims are disallowed. *See Young v. Bristol-Myers Squibb Co.*, No. 4:16-cv-00108, 2017 WL 706320, at *3 (N.D. Miss. 22 Feb. 2017). Instead, these claims must be evaluated under the framework of the MSPLA. *Ibid.* The *Young* court stated:

> Practically, where a common law claim is subsumed by the MPLA and is brought alongside products liability claims based on the same theory of recovery, the proper course is to dismiss the common law claim to the extent it is duplicative of the parallel products liability counts. To the extent a subsumed common law count is asserted "as an independent tort claim outside the scope of the MPLA," the count must be dismissed for failure to state a claim.

Id. at *4. As such, courts interpreting Mississippi law have regularly found that the MSPLA subsumes duplicative claims for breach of implied warranty, negligence, and unjust enrichment. *Elliott v. El Paso Corp.*, 181 So.3d 263, 269 n.24 (Miss. 2015) ["a negligence claim alleging failure to warn, train, educate, or draft a warning plan . . . is a claim based upon products liability, and such a claim must be analyzed under the M[S]PLA."]; *Arnoult v. CL Medical SARL*, No. 1:14-cv-271-KS-MTP, 2015 WL 5554301, *3 (S.D. Miss. Sept. 21, 2015) [the MPLA "specifically provides that it governs claims for breach of an implied warranty arising from damage caused by a product."]; *Knoth v. Apollo Endosurgery US, Inc.*, 425 F. Supp. 3d 678, 688 (S.D. Miss. 2019) [*finding* unjust enrichment claim subsumed]

Relying on this case law, the Court finds the MSPLA subsumes the PIMC common law claims for strict liability (all variants), negligence, negligence *per se*, breach of express warranty, breach of implied warranty, negligent misrepresentation, wrongful death, survival, loss of consortium, unjust enrichment, and punitive damages because they are duplicative of the product liability claims. However, the claim for violation of state consumer protection statutes is not duplicative and survives inasmuch as the MSPLA . appears not to preclude other statutory causes of action. *See, e.g.*, Miss. Code Ann. § 11–1–63.

As to the MMMC, the Court finds the MSPLA subsumes the common law claims for negligence, negligence *per se*, medical monitoring, strict liability (all variants, breach of implied warranty, and breach of express warranty.

Conversely, the MSPLA does not subsume claims relying on a theory that a consumer did not get the "benefit of the bargain". *See Childs v. Gen. Motors Corp.*, 73 F. Supp. 2d 669, 672 (N.D. Miss. 1999). Since the ELMC claims are properly governed by the UCC and seeks to recover for the economic losses suffered by Plaintiffs who allege that they did not get the "benefit of the bargain," the MSPLA does not subsume them.

Accordingly, the Court **GRANTS WITH PREJUDICE** the motion of Manufacturer Defendants motion and the incorporated-by-reference motions of the Wholesaler Defendants and the Pharmacy Defendants for those PIMC common law claims of strict liability (all variants), negligence, negligence *per se*, breach of express warranty, breach of implied warranty, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages; and

those MMMC common law claims of negligence, negligence *per se*, medical monitoring, strict liability (all variants) breach of implied warranty, and breach of express warranty, which arise under Mississippi law.

Accordingly, the Court **DENIES** the motion of the Manufacturer Defendants and the incorporated-by- reference motions of the Wholesaler Defendants and Pharmacy Defendants to dismiss In the PIMC for those common law claims for fraud as well as for the claim of violation of the state consumer protection law, which arise under Mississippi law.

Accordingly, the Court **DENIES** the motion of the Manufacturer Defendants and the incorporated-by- reference motions of the Wholesaler Defendants and Pharmacy Defendants to dismiss In the ELMC those common law claims for breach of express warranty, breach of implied warranty of merchantability and fitness, fraud; negligent misrepresentation, unjust enrichment, negligence, and negligence *per se* as well as claims for violation of state consumer protection laws, which arise under Mississippi LAW.

3.2.6 *NORTH CAROLINA*: PIMC:

Defendants contend that the North Carolina Product Liability Act ["NCPLA"], N.C. Gen. Stat. § 99B-1.1,. subsumes the strict liability claims in the PIMC, which plaintiffs do not rebut. Therefore, this Court finds the NCPLA subsumes plaintiffs' claims in the PIMC for strict liability.

Accordingly , the Court **GRANTS WITH PREJUDICE** the Manufacturer Defendants' motion and the incorporated -by-reference motions of the Wholesaler Defendants and the Pharmacy Defendants for those PIMC common law claims of strict liability (all variants) which arise under North Carolina law.

3.2.7 *OHIO*

3.2.7.1 OHIO PIMC AND MMMC

Defendants next contend the Ohio Product Liability Act ["OHPLA"], Ohio Rev. Code § 2307.72(A) & (B), subsumes many of plaintiffs' claims, but not the fraud claims. The OHPLA applies to "recovery of compensatory damages based on a product liability claim," in addition to "[a]ny recovery of punitive or exemplary damages in connection with a product liability claim.". "The O[hio] PLA has been held to abrogate claims for strict products liability, negligent failure to warn, breach of express warranty, and breach of implied warranty." *Mitchell v. Proctor & Gamble,* No. 2:09–CV–426, 2010 WL 728222, at *3 (S.D. Ohio Mar. 1, 2010) (and cases cited therein); *see also* Ohio Rev. Code § 2307.71(B) ("Sections 2307.71 to 2307.80 are intended to abrogate all common law product liability causes of action".).

However, "[c]laims of active misrepresentation (as opposed to failure to warn) in connection with a product are not abrogated by the O[H] PLA." *Boroff v. Alza Corp.,* 685 F. Supp. 2d 704, 711 (N.D. Ohio 2010) [*citing Hollar v. Philip Morris, Inc.*, 43 F. Supp. 2d 794, 809 (N.D. Ohio 1998) (*holding* that claims of active misrepresentation implicate a broader "duty not to deceive" and are thus not product liability claims barred by the OPLA)]; *see also Hogue v. Pfizer, Inc.,* 893 F.Supp.2d 914, 918 (S.D. Ohio 2012) [*explaining* "the OPLA does not abrogate fraud claims which are based on a general duty not to actively deceive; however, the OPLA does abrogate fraud claims arising from a duty to warn."]. Relying on this standard, the Court finds the OHPLA subsumes the PIMC claims for strict liability, negligence, negligence *per se*, breach of express warranty, breach of implied warranty, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages, but does not subsume the fraud claims.

As for the claim for relief under the state consumer protection acts, the court in *Traxler v. PPG Indus., Inc.*, 158 F. Supp. 3d 607, 628 (N.D. Ohio 2016) [interpreting Ohio law] noted that Ohio court cases hold both that the OPLA does and does not preempt a consumer protection claim (*See ibid.* [collecting cases]) with the determining factor being the kind of harm alleged by plaintiffs. The *Traxler* court also noted when personal injury is pleaded, the cases show that O[H]PLA affirmatively preempts consumer protection claims. *Ibid.* Inasmuch as the PIMC seeks personal injuries, this Court OHPLA subsumes the state consumer protection claim .

As to the MMMC, for the reasons articulated above, the OHPLA subsumes the claims for negligence, negligence *per se*, medical monitoring, strict liability (all variants), violation of Magnuson-Moss Warranty Act, breach of implied warranty, and breach of express warranty, but not the fraud claims.

Accordingly, the Court **GRANTS WITH PREJUDICE** the motion of the Manufacturer Defendants and the incorporated-by- reference motions of the Wholesaler Defendants and Pharmacy Defendants to dismiss:

1) in the PIMC those common law claims for strict liability (all variants), negligence, negligence *per se*, breach of express warranty, breach of implied warranty, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages as well as that claim for violation of the state consumer protection laws; and

2) in the MMMC the common law claims for negligence, negligence *per se*, medical monitoring, strict liability(all variants), breach of implied warranty, and breach of express warranty, which claims arise under Ohio law.

Accordingly, the Court **DENIES** the motion of the Manufacturer Defendants and the incorporated-by- reference motions of the Wholesaler Defendants and Pharmacy Defendants to dismiss: in the PIMC and the MMMC the common law fraud claims, which arise under Ohio law.

3.2.7.2 OHIO: ELMC.

As to the ELMC, the Court notes that "[a]ny recovery of compensatory damages for economic loss based on a claim that is asserted in a civil action, other than a product liability claim, is not subject to sections 2307.71 to 2307.79 of the [Ohio} Revised Code, but may occur under the common law of this state or other applicable sections of the Revised Code." Ohio R.C. 2307.72(c). Economic loss only includes "direct, incidental, or consequential pecuniary loss, including, but not limited to, damage to the product in question, and nonphysical damage to property other than that product." Ohio R.C. 2307.71(A)(2). In contrast to this definition, the OHPLA defines a product liability claim as seeking compensatory damages for "death, physical injury to person, emotional distress, or physical damage to property *other than the product in question*." Ohio R.C. 2307.71(A)(13) (emphasis added).

Seeks damages for the value of the defective VCDs, the ELMC claims are not product liability claims falling under OHPLA purview. S*ee LaPuma v. Collinwood Concrete,* 661 N.E.2d 714, 714 (Ohio 1996) ("Although a cause of action may concern a product, it is not a product liability claim within the purview of Ohio's product liability statutes unless it alleges damages other than economic ones, and a failure to allege other than economic damages does not destroy the claim, but rather removes it from the purview of those statutes.").

Accordingly, the Court **DENIES** the motion of the Manufacturer Defendants and the incorporated-by- reference motions of the Wholesaler Defendants and Pharmacy Defendants to dismiss those common law claims in the ELMC for breach of express warranty, breach of implied warranty of merchantability and fitness, fraud; negligent misrepresentation, unjust enrichment, negligence, and negligence *per se* as well as claims for violation of state consumer protection laws, which arise under Ohio law.

3.2.8 TENNESSEE: PIMC, MMMC, and ELMC

Defendants next assert the Tennessee Product Liability Act ["TNPLA"], Tenn. Code Ann. § 29–28–101 *et seq.*, subsumes all claims. The TNPLA is the exclusive avenue for bringing claims relating to allegedly defective products. *See* Tenn. Code Ann. § 29–28–102 [*defining* the term "product liability actions" broadly: all actions based upon . . . strict liability in tort; negligence; breach of warranty, express or implied . . . or under any other substantive legal theory in tort or contract whatsoever"]. Therefore, courts applying Tennessee law have found the TNPLA subsumes these common law claims, but have allowed claims for violation of state consumer protection statutes to prevail. *See, e.g.*, *Fleming v. Janssen Pharmaceuticals, Inc.*, 186 F. Supp. 3d 826, 834 (W.D. Tenn. 2016).

Relying on this case law, this Court finds the TNPLA subsumes the PIMC common law claims for strict liability (all variants), negligence, negligence *per se*, breach of express warranty, breach of implied warranty, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages. Similarly, for the reasons articulated above, the TNPLA MMMC subsumes the common law claims for negligence, negligence *per se*, medical monitoring, manufacturing defect, failure to warn, breach of implied warranty, breach of express warranty, and fraud.

As to the ELMC, the Tennessee Supreme Court has held that actions under the Tennessee PLA are limited to those brought on account of personal injury, death, or property damage and do not include actions brought for pecuniary loss. *See First Nat'l. Bank of Louisville v. Brooks Farms,* 821 S.W.2d 925, 930–31 (Tenn. 1991). The ELMC seeks damages for pecuniary loss, not damages for personal injury, death, or property damage. Therefore, the ELMC falls outside the purview of the Tennessee PLA, and these claims are not subsumed. *See Lincoln Gen. Ins. Co. v. Detroit Diesel Corp.*, 293 S.W.3d 487, 489 (Tenn. 2009).

Accordingly, the Court **GRANTS WITH PREJUDICE** the motion of the Manufacturer Defendants and the incorporated-by- reference motions of the Wholesaler Defendants and Pharmacy Defendants to dismiss:

1) in the PIMC those common law claims for strict liability (all variants), negligence, negligence *per se*, breach of express warranty, breach of implied warranty, fraud, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages; and

2) in the MMMC the common law claims for negligence, negligence *per se*, medical monitoring, strict liability(all variants), fraud, breach of implied warranty, and breach of express warranty, which claims arise under Tennessee law.

Accordingly, the Court **DENIES** the motion of the Manufacturer Defendants and the incorporated-by- reference motions of the Wholesaler Defendants and Pharmacy Defendants to dismiss: in the PIMC and the MMMC the claims for violation of state consumer protection statutes, which arise under Tennessee law.

Accordingly, the Court **DENIES** the motion of the Manufacturer Defendants and the incorporated-by- reference motions of the Wholesaler Defendants and Pharmacy Defendants to dismiss those common law claims in the ELMC for breach of express warranty, breach of implied warranty of merchantability and fitness, fraud; negligent misrepresentation, unjust enrichment, negligence, and negligence *per se* as well as claims for violation of state consumer protection laws, which arise under Tennessee law.

3.2.9 *WASHINGTON*: PIMC, MMMC, and ELMC

Defendants last assert the Washington Product Liability Act ["WAPLA"], Wash. Rev. Code Ann. § 7.72.010 *et seq.*, subsumes many of Plaintiffs' claims, but not a claim for a claim for violation of state consumer protection statues. The WAPLA recognizes only a single product liability cause of action. . *See* Wash. Rev. Code Ann. § 7.72.010(4) [*defining* "product liability claim" broadly as strict liability, negligence, breach of express or implied warranty and failure to warn claims]. *See also Macias v. Saberhagen Holdings, Inc.*, 282 P.3d 1069, 1073–74 (2012) ["The W[A]PLA is the exclusive remedy for product liability claims. It supplants all common law claims or actions based on harm caused by a product." (internal citations omitted)]. *See also*, *Wash. State Physicians Ins. Exchange & Ass'n v. Fisions Corp.*, 858 P.2d 1054, 1066 (Wash. 1993) *[holding* "The [WA] PLA preempts traditional common law remedies for product-related harms."]

The WA PLA at Wash. Rev. Code Ann. § 7.72.010(4) defines a "product liability claim" as any "claim or action brought for harm caused by the production, making, construction, fabrication, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging, storage or labeling of the relevant product", which also includes any claiim previously based on "[s]trict liability in tort; negligence; breach of express or implied warranty; breach of, or failure to, discharge a duty to warn or instruct whether negligent or innocent; misrepresentation, concealment, or

nondisclosure, whether negligent or innocent" *Ibid.* The only claims not subsumed are those for "fraud, intentionally caused harm[,] or a claim or action under the consumer protection act." *Ibid.*

As used in the WAPLA, the term 'harm ' does "not include "direct or consequential economic loss" (*Hofstee v. Dow*, 36 P.3d 1073, 1077 (Wash. Ct. App. 2001) (internal citation omitted)), which "covers two general areas of damages: (1) direct economic loss based on inadequate product value, measured by the cost to repair and replace the defective product; and (2) indirect or consequential loss proximately caused by the loss of use of the product (e.g., lost profits)." *Ibid.*

Based on this standard, the Court finds the WAPLA subsumes the following common law claims in the PIMC: strict liability, negligence, negligence *per se*, breach of express warranty, breach of implied warranty, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages, but not those for fraud or violation of the state consumer protection statutes. Likewise, the Court finds the WAPLA subsumes the following common claims in the MMMC are subsumed: negligence, negligence *per se*, medical monitoring, manufacturing defect, failure to warn, breach of implied warranty, and breach of express warranty, but not those for fraud .

Since the ELMC claims seek to recover economic loss suffered due to the receipt of contaminated VCDs and since such loss does not fall within the purview of "harm' in the WAPLA, the Court finds the WAPLA does not subsume these claims.

Accordingly, the Court **GRANTS WITH PREJUDICE** the motion of the Manufacturer Defendants and the incorporated-by- reference motions of the Wholesaler Defendants and Pharmacy Defendants to dismiss:

1) in the PIMC those common law claims for strict liability (all variants), negligence, negligence *per se*, breach of express warranty, breach of implied warranty, negligent misrepresentation, wrongful death, survival, loss of consortium, and punitive damages; and

2) in the MMMC the common law claims for negligence, negligence *per se*, medical monitoring, strict liability(all variants), breach of implied warranty, and breach of express warranty, which claims arise under Washington law.

Accordingly, the Court **DENIES** the motion of the Manufacturer Defendants and the incorporated-by- reference motions of the Wholesaler Defendants and Pharmacy Defendants to dismiss: in the PIMC and the MMMC the common law claims for fraud as well as the claim for violation of state consumer protection statutes, which arise under Washington law.

Accordingly, the Court **DENIES** the motion of the Manufacturer Defendants and the incorporated-by- reference motions of the Wholesaler Defendants and Pharmacy Defendants to dismiss those common law claims in the ELMC for breach of express warranty, breach of implied warranty of merchantability and fitness, fraud; negligent misrepresentation, unjust enrichment, negligence, and

negligence *per se* as well as claims for violation of state consumer protection laws, which arise under Washington law.

.

4.0 NEGLIGENCE *PER SE*

4.1 WHETHER THE COMPLAINTS STATE A CLAIM FOR NEGLIGENCE *PER SE*

Manufacturer Defendants argue that the ELMC and MMMC fail to state a claim for negligence *per se* because the complaints "are devoid of any allegation that the statutes, regulations, and cGMPs they claim were violated were intended to protect Plaintiffs." ECF Doc. 520 at 43. Therefore, these defendants argue that these claims should be dismissed in the states whose law requires this element. The MMMC pleads that "[e]ach Defendant owed a duty to Plaintiffs and the Class because each state, territory, and possession has adopted /or adheres to federal cGMP and adulteration standards." MMMC ¶409. The ELMC pleads similar allegations. ELMC ¶591. Therefore, the Court considers whether the cGMPs were intended to protect the Plaintiffs asserting claims under the MMMC and the ELMC.

Plaintiffs plead that, under federal law, "pharmaceutical drugs must be manufactured in accordance with 'current Good Manufacturing Practices' ('cGMPs') to ensure they meet safety, quality, purity, identity, and strength standards." MMMC ¶188 [*citing* 21 U.S.C. § 351(a)(2)(B)]. The cGMPs establish "minimum current good manufacturing practices for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety[] and has the identity and strength and meets the quality of purity characteristics that it purports or is represented to possess." 21 C.F.R. § 210.1(a). The FDA has stated that the cGMPs were created to "make sure that a [drug] product is safe for use, and that it has the ingredients and strength it claims to have."[9]

Based on the regulations and the FDA's guidance, the Court finds that the cGMPs were intended to protect individuals consuming and purchasing drug products from harm caused by unsafe drug products lacking the ingredients and strength they claim to have. Further, the Court finds that those plaintiffs seeking relief under the MMMC and the ELMC are in the very class of individuals the cGMPs were intended to protect.

As to the MMMC, plaintiffs claim that they have suffered cellular damage and genetic harm and are at an increased risk of developing cancers due to the VCDs. These Plaintiffs undoubtedly fall within the class of individuals that the FDA intended to protect with the promulgation of the cGMPs. There is no doubt the purpose of the cGMPs was to prevent consumers from ingesting drugs that cause cellular

[9] *Current Good Manufacturing Practice (CGMP) Regulations*, U.S. Food & Drug Admin., https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations (last accessed 10 Jan. 2021).

damage and could potentially cause cancer. Therefore, medical monitoring plaintiffs fall within the class of individuals the cGMPs are intended to protect.

As to the ELMC, plaintiffs claim they overpaid for the VCDs because these drugs were not what they purported to be. Although more attenuated, it is at least a reasonable and likely argument that, in instituting the cGMPs, the FDA also intended to protect those individuals who purchased drugs by ensuring that they did in fact receive drugs containing the ingredients they expected based on the manufacturers' representations of those drugs.

The Court finds that the cGMPs were intended to protect these classes of plaintiffs. Accordingly, at this general stage of the argumentation, the Court **DENIES** Defendants' motion to dismiss the common law claims of negligence *per se.*

4.2 WHETHER THE NEGLIGENCE *PER SE* CLAIMS ARE COGNIZABLE AS INDEPENDENT CAUSES OF ACTION

However, defendants also argue specifically that "[a] number of states do not recognize negligence *per se* as a separate cause of action[.]" ECF Doc. 520 at 43–44. The Court recognizes that the following states do not recognize a stand-alone cause of action for negligence *per se*: Arkansas[10]; Arizona[11]; California[12]; Massachusetts[13]; Maine[14]; Nebraska[15]; Rhode Island[16]; and Texas.[17]

Accordingly, the Court **GRANTS WITH PREJUDICE** defendants' motion to dismiss a stand-alone, common law claim in the PIMC, MMMC, or the ELMC for negligence *per se*, which arises under the laws of Arkansas; Arizona; California; Massachusetts; Maine; Nebraska; Rhode Island; and Texas. However, the Court expressly states this grant does not affect or prejudice plaintiffs' ability to use evidence of the violation of a statute to support their negligence claims.[18]

---

[10] *Central Okla. Pipeline, Inc. v. Hawk Field Servs., LLC*, 400 S.W.3d 701, 712 (Ark. 2012) ("Under Arkansas law, the violation of a statute is only evidence of negligence and does not constitute negligence *per se*.").

[11] *Udd v. City of Phoenix*, No. 18-01616, 2020 WL 1536326, at *26 (D. Ariz. Mar. 31, 2020) ("Negligence *per se* is not a cause of action separate from common law negligence.").

[12] *Millard v. Biosources, Inc.*, 156 Ca. App. 4th 1338, 1353 n.2 (Cal. Ct. App. 2007) ("the doctrine of negligence *per se* is not a separate cause of action, but creates an evidentiary presumption that affects the standard of care in a cause of action for negligence.").

[13] *Deutsche Lufthansa AG v. Mass. Port Auth.*, No. 17-11702, 2018 WL 3466938, at *2 (D. Mass. July 18, 2018) ("The Supreme Judicial Court has repeatedly reaffirmed the principle that negligence *per se* does not exist as a cause of action independent from a general negligence action[.]").

[14] *Elliott v. S.D. Warren Co.*, 134 F.3d 1, 5 (1st Cir. 1998) ("under Maine's common law the violation of a safety statute is merely evidence of negligence, not negligence *per se*.").

[15] *Scheele v. Rains*, 874 N.W.2d 867, 873 (Neb. 2016) ("we have held that the violation of a regulation or statute is not negligence *per se*, but may be evidence of negligence to be considered with all the other evidence in the case.") (citation omitted).

[16] *Kurczy v. St. Joseph Veterans Ass'n, Inc.*, 820 A.2d 929, 947 (R.I. 2003).

[17] *Johnson v. Enriquez*, 460 S.W.3d 669, 673 (Tex. Ct. App. 2015) ("Negligence *per se* is not a separate cause of action independent of a common-law negligence cause of action.") (citation omitted).

[18] Defendants additionally argue that negligence *per se* is not permitted as a separate cause of action under the laws of Louisiana, Kentucky, and South Carolina.

As for Louisiana, the Court does not address the negligence *per se* claim there because the Court has already held that the negligence *per se* claims are subsumed by the Louisiana PLA. *See supra* Section 3.2.

4.0 NEGLIGENCE

4.1 WHETHER THE ECONOMIC LOSS RULE BARS PLAINTIFFS' CLAIMS

Defendants contend the negligence claims should be dismissed because the " ELMC and MMMC do not allege current physical injury or property damage resulting from Defendants' VCDs" (ECF Doc.520-3:44), which therefore bars these claims by the economic loss rule in forty-one states. In their opposition, plaintiffs assert that "many states which follow the economic loss rule actually carve out notable exceptions to the rule". ECF Doc. No. 577:83. Thus, determining whether a negligence claim has been properly pleaded under the law of these 41 states requires a fact-intensive determination that makes "dismissal premature at the 12(b)(6) stage." *Ibid.* The Court agrees.

Courts in the Third Circuit have declined to rule on economic loss arguments at the motion to dismiss phase, noting resolving whether the economic loss rule applies requires a "fact-intensive inquiry". *See, e.g.*, *Covertech Fabricating, Inc. v. TVM Building Prods., Inc.*, 2014 WL 2605427, at *6 (W.D. Pa.11 June 2014). Limiting its review properly to the confines of the Master Complaints, the Court lacks adequate information at this state to assess whether the economic loss rule bars plaintiffs' claims. Accordingly, the Court declines at this to rule on the applicability of the economic loss rule without a more developed factual record, which holding does not preclude defendants from raising this argument in their summary judgment motions.

4.2 WHETHER THE COMPLAINTS STATE A CLAIM FOR NEGLIGENCE AGAINST WHOLESALER AND PHARMACY DEFENDANTS

Pharmacy Defendants contend the negligence claims against them should be dismissed because they "do not have a duty to test or inspect dispensed drugs," and therefore "Plaintiffs cannot plausibly state a claim that the Pharmacies should have known of the alleged valsartan impurity." ECF Doc. 523:20. Wholesaler Defendants similarly argue the Master Complaints fail to state a claim for negligence against them ECF Doc. 522:27.

The Court recognizes in this Circuit the prerequisites to a negligence claim aee the existence of a legal duty and its breach. *Smith v. Sci. Games Corp.*, 461 F. App'x 151, 153 (3d Cir. 2012) ["Whether there is a duty of care is a matter of law for the court to decide."]. Moreover, a review of the case law from potential jurisdictions reveals duty and breach are universal requirements of a negligence claim.

As for Kentucky, the Court rejects this argument because Kentucky has codified the common law doctrine of negligence *per se*. *See Tassin v. BNK Transport Inc.*, No. 19-00064, 2019 WL 2271163, at *2 (W.D. Ky. 28 May 2019) [*citing* K.R.S. § 446.070).

As for South Carolina, the Court rejects defendants' argument about negligence *per se* claims there inasmuch as, under some circumstances, South Carolina does allow an independent cause of action for negligence *per se* to be litigated. Therefore, since the proper pleading of a common law, stand-alone negligence *per cl*aim under South Carolina is a question of fact, at this stage of the proceedings, dismissing it is premature. *See, e.g.*, *Wellin v. Wellin*, 135 F. Supp. 3d 502, 528 (D.S.C. 2015).

Therefore, the Court considers whether the plaintiffs adequately pleaded in the Master Complaints the existence of a duty and its breach by the Wholesalers and the Pharmacies.

In their Opposition, plaintiffs assert several, different theories as to duty and breach regarding these defendant groups. First, plaintiffs argue, "Wholesaler Defendants and Retail Pharmacy Defendants breached their common law duties to appropriately vet their generic manufacture suppliers to ensure that they did not sell adulterated, misbranded[,] and/or contaminated product." ECF Doc. 577:81. Second, plaintiffs argue the Pharmacy Defendants have a duty to "use due and proper care in filling prescriptions and selling products to the public." *Ibid.* Third, plaintiffs contend "Wholesaler Defendants had duties to exercise reasonable care in their acquisition and re-sale of products". *Id:* 82.)

Although plaintiffs make these assertions in their Opposition, the Master Complaints lack allegations to support each of these arguments, which is amplified by the fact that plaintiffs do not cite to the Master Complaints or their allegations when opposing the Motions to Dismiss on this point. While each of plaintiffs' aforementioned assertions of duty and breach could potentially suffice to state a claim, the Master Complaints are devoid of factual allegations to support such statements. Rather, as noted in this Court's MTD Opinion 2 (ECF Doc. 728), the Master Complaints lump Defendants together with conclusory allegations, which fail to separate the alleged negligent conduct of the Wholesaler Defendants from that of the Pharmacy Defendants. In other words, the Master Complaints fail to precisely articulate the duty that the Pharmacy Defendants and the Wholesaler Defendants owed to Plaintiffs and the specific breach that occurred. Without these allegations, the Court cannot determine whether Plaintiffs have stated a claim for negligence as to the Pharmacy and Wholesaler Defendants. Moreover, the Pharmacy and Wholesaler Defendants are left without adequate notice of plaintiffs' theories of negligence.

Accordingly, the Court GRANTS WITHOUT PREUDICE the Pharmacy Defendants' and the Wholesaler Defendants' motions to dismiss the common law negligence claims in the three Master Complaints.

Plaintiffs may file a motion for leave to amend the negligence claims against the Pharmacy Defendants' and the Wholesaler Defendants in the Master Complaints according to the deadline provided in the accompanying Order, but only to the extent that such amendments do not supersede the Subsumption rulings *supra.*

5.0 MEDICAL MONITORING

Defendants next argue that Plaintiffs' stand-alone claims for medical monitoring should be dismissed because many jurisdictions do not recognize such a claim. ECF Doc. 520-3: 53 accompanied by the chart of state jurisdictions in ECF Doc. 520-5: 57–58. In their Opposition, plaintiffs assert Defendants'

chart misstates the applicable law and advance their own chart as correctly identifying which states do not recognize these claims.. ECF Doc. 57 7-97 -98; ECF Doc. 577-Appendix 2: 5-10.

The Court divides its holding into three parts:

First, the Court recognizes that, even though Alabama[19]; Arkansas[20]; Connecticut[21]; Georgia[22]; Kentucky[23]; Louisiana[24]; Michigan[25]; Mississippi[26]; Nebraska[27]; New Jersey[28]; Oklahoma[29]; South Carolina[30]; Tennessee[31]; Texas[32]; Virginia[33]; and Wisconsin.[34] may not recognize independent claims for medical monitoring , they may, however, may allow a plaintiff under certain circumstances to recover damages for medical monitoring premised on another tort:

Accordingly, the Court **GRANTS WITHOUT PREJUDICE** Defendants' motions to dismiss in the MMMC those independent claims for medical monitoring, which arise under the laws of Alabama, Arkansas, Connecticut, Georgia, Kentucky, Louisiana, Michigan, Mississippi, Nebraska, New Jersey, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and Wisconsin. However, this ruling does not affect or prejudice plaintiffs' seeking recovery for medical monitoring in concert with any other claim in accordance with the law of those jurisdictions.

Second, the Court recognizes that Indiana[35]; Iowa[36]; and New Hampshire[37] have either not, or inconsistently, ruled on allowing an independent medical monitoring claim. Accordingly, the Court

---

[19] *Houston Cnty. Health Care Auth. v. Williams*, 961 So. 2d 795, 811 (Ala. 2006).
[20] *Baker v. Wyeth-Ayerst Laboratories Div.*, 992 S.W.2d 797, 799 (Ark. 1999).
[21] *Dougan v. Sikorsky Aircraft Corp.*, —A.3d—, 2020 WL 5521391 (Conn. Sept. 14, 2020).
[22] *Parker v. Brush Wellman, Inc.*, 777 F. Supp. 2d 1290, 1302 (N.D. Ga. 2005).
[23] *Wood v. Wyeth-Ayerst Labs*, 82 S.W.3d 849, 859 (Ky. 2002).
[24] La. Civ. Code Ann. art. 2315.
[25] *Henry v. Dow Chem. Co.*,701 N.W.2d 684, 686 (Mich. 2005).
[26] *Paz v. Brush Engineered Materials, Inc.*, 949 So. 2d 1 (Miss. 2007).
[27] *Avila v. CNH Am.*, LLC, No. 4:04-cv-3384, 2012 WL 13187721, at *5 (D. Neb. Aug. 30, 2012) (predicting that Nebraska would not allow independent cause of action).
[28] *Sinclair v. Merck & Co.*, 948 A.2d 587, 595 (N.J. 2008).
[29] *Cole v. ASARCO Inc.*, 256 F.R.D. 690, 695 (N.D. Okla. 2009).
[30] *Rosmer v. Pfizer, Inc.*, No. 9:99-cv-228018, 2001 WL 34010613, at *5 (D.S.C. Mar. 30, 2001) (predicting that South Carolina courts would not allow medical monitoring as independent claim).
[31] *Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568, 576 n.7 (6th Cir. 2005).
[32] *Norwood v. Raytheon Co.*, 414 F. Supp. 2d 659, 666 (W.D. Tex. 2006) (predicting Texas courts would not recognize independent claim).
[33] *Ball v. Joy Techs., Inc.*, 958 F.2d 36, 39 (4th Cir. 1991) (predicting that Virginia would not recognize an independent claim).
[34] *Alsteen v. Wauleco, Inc.*, 802 N.W.2d 212, 219 (Wis. Ct. App. 2011).
[35] Courts applying Indiana law have come to differing conclusions. *Compare Hunt v. American Wood Preservers Institute*, No. 02-0389, 2002 WL 34447541, at *1 (S.D. Ind. July 31, 2002) *with Allgood v. General Motors Corp.*, No. 102CV1077DFHTAB, 2005 WL 2218371, at *6–8 (S.D. Ind. Sept. 12, 2005).
[36] Iowa has not explicitly accepted or rejected medical monitoring as an independent cause of action or as a remedy. *Manvill Corp. Asbestos Disease Compensation Fund*, 496 N.W.2d 247 (Iowa 1993); *but see Pickrell v. Sorin Grp. USA, Inc.*, 293 F. Supp. 3d 865, 868 (S.D. Iowa 2018) (predicting that Iowa would not adopt a medical monitoring cause of action, or if it did, the court would require an actual injury).
[37] *Brown v. Saint-Gobain Performance Plastics Corp.*, No. 16-cv-242, 2018 WL 10638396, at *1 (D.N.H. Dec. 6, 2018) (noting that New Hampshire has neither accepted nor rejected medical monitoring claim).

DENIES Defendants' motions to dismiss in the MMMC those independent claims for medical monitoring, which arise under the laws of Indiana, Iowa, and New Hampshire.

Third, the Court recognizes that North Carolina[38] has rejected outright an independent medical monitoring claim as well as a medical monitoring claim as the measure of damages. Accordingly, the Court **GRANTS WITH PREJUDICE** defendants' motions to dismiss in the MMMC those independent claims for medical monitoring, which arise under North Carolina law. .

6.0 STRICT LIABILITY

Pharmacy Defendants assert that courts have uniformly held that pharmacies are not subject to strict liability for latent defects in drugs they dispense. ECF Doc. 523 at 11. In their Opposition, plaintiffs argue this assertion is incorrect because a number of states have actually adopted a rule allowing "any seller in the chain of distribution" to be liable "for the sale of a defective product that was a cause of the plaintiff's injury." ECF Doc. 577: 99 [*citing* Restatement (3d) of Torts: Prod. Liab. § 1 (1998)].

Moreover, the Pharmacy Defendants make broad policy arguments regarding why the Court should not hold pharmacies strictly liable (*See, e.g.*, ECF Doc. 523:11–13), which the Court declines to accept as sufficient to dismiss all of plaintiffs' strict liability claims against Pharmacy Defendants. In further support of their motion to dismiss arguments, Pharmacy Defendants appended a State-By-State Summary Chart (ECF Doc. 523-3) in which they précis cases from various states in an attempt to demonstrate that these states do not hold pharmacies strictly liable for the sale of a valid prescription. *Id.* The Court has reviewed the cited cases in the Summary Chart to confirm the accuracy of Pharmacies' assertions as to which states hold pharmacies strictly liable for the drugs they sell. As articulated in its prior Opinion, the Court looked for jurisdictions where the Pharmacies' assertions did not apply or where the law was unclear and did not consider arguments regarding innocent seller statutes in this portion of its Opinion.

Accordingly, the Court **GRANTS WITHOUT PREJUDICE** the Pharmacy Defendants' motion to dismiss in any of the Master Complaints those strict liability claims in Alabama[39]; Arizona[40]; Arkansas[41];

[38] *Curl v. Am. Multimedia, Inc.*, 654 S.E.2d 76, 81 (N.C. Ct. App. 2007).
[39] *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, No. 3:11–cv–20153, 2012 WL 1831789, at *4 (S.D. Ill. May 18, 2012).
[40] *Strong v. Merck & Co*, No. CV 2005-053195, 2009 WL 7233281 (Ariz. Super. Ct. Nov. 09, 2009).
[41] *Kohl v. Am. Home Prods. Corp.*, 78 F. Supp. 2d 885, 896 (W.D. Ark. 1999).

California[42]; Connecticut[43]; District of Columbia[44]; Florida[45]; Georgia[46]; Hawaii[47]; Illinois[48]; Iowa[49]; Louisiana[50]; Maine[51]; Maryland[52]; Massachusetts[53]; Michigan[54]; Mississippi[55]; New Hampshire[56]; New Jersey[57]; New Mexico[58]; New York[59]; North Carolina[60]; Oklahoma[61]; Pennsylvania[62]; Tennessee[63]; Utah[64]; Virginia[65]; Washington[66]; and West Virginia.[67]

Accordingly, the Court **DENIES** the Pharmacy Defendants' motion to dismiss in any of the three Master Complaints the claims for strict liability, which arise under the laws of Alaska; Colorado; Delaware; Idaho; Indiana; Iowa; Kansas; Kentucky; Minnesota; Missouri; Montana; Nebraska; Nevada; Ohio; Oregon; Puerto Rico; Rhode Island; South Carolina; South Dakota; Texas; Vermont; Wisconsin; or Wyoming. However, the Court acknowledges that its subsumption holdings *supra* in this Opinion may affect this denial.

7.0 CONCLUSION

For the reasons discussed above, the Court rules as follows to resolve defendants' arguments relating to the subsumption of common law claims by various states' Products Liability Acts and to the Rule 12(b)(6) pleading deficiencies for common law claims of negligence, negligence *per se* against all three categories of defendants as well as common law claims of strict liability claims against the Pharmacy Defendants: .

---

[42] *Murphy v. E.R. Squibb & Sons, Inc.*, 710 P.2d 247, 251 (Cal. 1985).
[43] *Altieri v. CVS Pharm.*, No. X06CV020171626S, 2002 WL 31898323, at *4–5 (Conn. Super. Ct. Dec. 13, 2002).
[44] *Ealy v. Richardson-Merrell, Inc.*, No. 83–3504, 1987 WL 159970, at *3 (D.D.C. Jan. 12, 1987).
[45] *McLeod v. W. S. Merrell Co.*, 174 So. 2d 736, 739 (Fla. 1965).
[46] *Robinson v. Williamson*, 537 S.E.2d 159, 161 (Ga. Ct. App. 2000).
[47] *Birmingham v. Fodor's Travel Publ'ns, Inc.*, 833 P.2d 70, 79 (Haw. 1992).
[48] *Jones v. Irvin*, 602 F. Supp. 399, 400 (S.D. Ill. 1985).
[49] *Merfeld v. Domestic Corp.*, 306 F. Supp. 3d 1070, 1076-78 (N.D. Iowa 2018) (granting summary judgment for retailer), *aff'd*, 940 F.3d 1017 (8th Cir. 2019).
[50] *Zehner v. Nordskog Indus., Inc.*, No. 92-2508, 1992 WL 233984, at *3 (E.D. La. Sept. 2, 1992).
[51] *Herzog v. Arthrocare Corp.*, No. Civ. 02-76-P-C, 2003 WL 1785795, at *13 (D. Me. Mar. 21, 2003).
[52] *Rite-Aid Corp. v. Levy-Gray*, 894 A.2d 563, 578 (Md. 2006).
[53] *Carrozza v. CVS Pharmacy*, 391 F. Supp. 3d 136, 147 (D. Mass. 2019)
[54] *Adkins v. Mong*, 425 N.W.2d 151, 152 (Mich. Ct. App. 1988).
[55] *In re Rezulin Prods. Liab. Litig.*,133 F.Supp.2d 272, 288-90 (S.D.N.Y. 2001).
[56] *Siciliano v. Capitol City Shows, Inc.*, 475 A.2d 19, 25 (N.H. 1984).
[57] *Feldman v. Lederle Labs.*, 479 A.2d374, 380–81 (N.J. 1984).
[58] *Ruiz v. S. Pac. Transp. Co.*, 638 P.2d 406, 412 (N.M. Ct. App. 1981).
[59] *Ullman v. Grant*, 450 N.Y.S.2d 955, 957 (N.Y. Sup. Ct. 1982).
[60] *Batiste v. Am. Home Prods. Corp.*, 231 S.E.2d 269, 275–76 (N.C. Ct. App. 1977).
[61] *White v. Mylan, Inc.*, No. CIV-12-402-D, 2012 WL 6726593, at *3 (W.D. Okla. Dec. 27, 2012).
[62] *Ramirez v. Richardson-Merrell, Inc.*, 628 F. Supp. 85, 86 (E.D. Pa. 1986).
[63] *Heaton v. Mathes*, No. E2019-00493-COA-R9-CV, 2020 WL 1652571, at *7–8 (Tenn. Ct. App. Apr. 3, 2020).
[64] *Shaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 928–32 (Utah 2003).
[65] *Evans v. NACCO Materials Handling Grp., Inc.*, 810 S.E.2d 462, 469 (Va. 2018).
[66] *McKenna v. Harrison Mem'l Hosp.*, 960 P.2d 486, 488 (Wash. Ct. App. 1998).
[67] *Ashworth v. Albers Med., Inc.*, 395 F. Supp. 2d 395, 405–06 (S.D. W. Va. 2005).

AS FOR SUBSUMPTION:

As to the Personal Injury Master Complaint claims arising under the laws of New Jersey: the Court finds that all claims—except breach of express warranty—are subsumed by the New Jersey Products Liability Act; therefore, the Court **GRANTS** all Defendants' Motion to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Medical Monitoring Master Complaint claims arising under the laws of New Jersey: the Court finds that all claims—except breach of express warranty and violation of the Magnuson-Moss Warranty Act—are subsumed by the New Jersey Products Liability Act; therefore, the Court **GRANTS** all defendants' Motions to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Economic Loss Master Complaint claims arising under the laws of New Jersey: the Court finds none of these claims are subsumed by the New Jersey Products Liability Act; therefore the Court **DENIES** the Motion to Dismiss these claims.

As to the Personal Injury Master Complaint claims arising under the laws of Connecticut: the Court finds that all claims are subsumed by the Connecticut Products Liability Act; therefore, the Court **GRANTS** all defendants' Motions to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Medical Monitoring Master Complaint claims arising under the laws of Connecticut: the Court finds that all claims are subsumed by the Connecticut Products Liability Act; therefore, the Court **GRANTS** all defendants' Motions to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Economic Loss Master Complaint claims arising under the laws of Connecticut: the Court finds that none of the claims are subsumed by the Connecticut Products Liability Act; therefore, the Court **DENIES** the Motion to Dismiss these claims.

As to the Personal Injury Master Complaint claims arising under the laws of Indiana: the Court finds that all claims—except for violation of state consumer protection statutes, breach of express warranty, and breach of implied warranty—are subsumed by the Indiana Products Liability Act; therefore, the Court **GRANTS** all Defendants' Motion to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Medical Monitoring Master Complaint claims arising under the laws of Indiana: the Court finds that all claims—except the claims for breach of implied warranty, breach of express warranty, and violation of Magnuson-Moss Warranty Act—are subsumed by the Indiana Products Liability Act; therefore, the Court **GRANTS** all Defendants' Motion to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Economic Loss Master Complaint claims arising under the laws of Indiana: the Court finds that none of the claims are subsumed by the Indiana Products Liability Act; therefore, the Court **DENIES** the Motion to Dismiss these claims.

As to the Personal Injury Master Complaint claims arising under the laws of Kansas: the Court finds that all claims—except the claim for violation of state consumer protection statutes—are subsumed by the Kansas Products Liability Act; therefore, the Court **GRANTS** all Defendants' Motion to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Medical Monitoring Master Complaint claims arising under the laws of Kansas: the Court finds that all claims are subsumed by the Kansas Products Liability Act; therefore, the Court **GRANTS** all Defendants' Motion to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Economic Loss Master Complaint claims arising under the laws of Kansas: the Court finds that none of the claims are subsumed by the Kansas Products Liability Act; therefore, the Court **DENIES** the Motion to Dismiss these claims.

As to the Personal Injury Master Complaint claims arising under the laws of Louisiana: the Court finds that all claims are subsumed by the Louisiana Products Liability Act; therefore, the Court **GRANTS** all Defendants' Motion to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Medical Monitoring Master Complaint claims arising under the laws of Louisiana: the Court finds that all claims are subsumed by the Louisiana Products Liability Act; therefore, the Court **GRANTS** all Defendants' Motion to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Economic Loss Master Complaint claims arising under the laws of Louisiana: the Court finds that all claims are subsumed by the Louisiana Products Liability Act; therefore, the Court **GRANTS** all Defendants' Motion to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Personal Injury Master Complaint claims arising under the laws of Mississippi: the Court finds that all claims—except the claims for fraud and violation of state consumer protection statutes—are subsumed by the Mississippi Products Liability Act; therefore, the Court **GRANTS** all Defendants' Motion to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Medical Monitoring Master Complaint claims arising under the laws of Mississippi: the Court finds that all claims—except the fraud claim—are subsumed by the Mississippi Products Liability Act; therefore, the Court **GRANTS** all Defendants' Motion to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Economic Loss Master Complaint claims arising under the laws of Mississippi: the Court finds that none of the claims are subsumed by the Mississippi Products Liability Act; therefore, the Court **DENIES** the Motion to Dismiss these claims.

As to the Personal Injury Master Complaint claims arising under the laws of North Carolina: the Court finds that the strict liability claims are subsumed by the North Carolina Products Liability Act; therefore, the Court **GRANTS** all Defendants' Motion to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Personal Injury Master Complaint claims arising under the laws of Ohio: the Court finds that all claims—except the claim for fraud—are subsumed by the Ohio Products Liability Act; therefore, the Court **GRANTS** all Defendants' Motion to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Medical Monitoring Master Complaint claims arising under the laws of Ohio: the Court finds that all claims—except the claim for fraud—are subsumed by the Ohio Products Liability Act; therefore, the Court **GRANTS** all Defendants' Motion to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Economic Loss Master Complaint claims arising under the laws of Ohio: the Court finds that none of the claims are subsumed by the Ohio Products Liability Act; therefore, the Court **DENIES** the Motion to Dismiss these claims.

As to the Personal Injury Master Complaint claims arising under the laws of Tennessee: the Court finds that all claims—except the claim for violation of state consumer protection statutes—are subsumed by the Tennessee Products Liability Act; therefore, the Court **GRANTS** all Defendants' Motion to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Medical Monitoring Master Complaint claims arising under the laws of Tennessee: the Court finds that all claims are subsumed by the Tennessee Products Liability Act; therefore, the Court **GRANTS** all Defendants' Motion to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Economic Loss Master Complaint claims arising under the laws of Tennessee: the Court finds that none of the claims are subsumed by the Tennessee Products Liability Act; therefore, the Court **DENIES** the Motion to Dismiss these claims.

As to the Personal Injury Master Complaint claims arising under the laws of Washington: the Court finds that all claims—except the claims for violation of state consumer protection statutes and fraud—are subsumed by the Washington Products Liability Act; therefore, the Court **GRANTS** all Defendants' Motion to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Medical Monitoring Master Complaint claims arising under the laws of Washington: the Court finds that all claims—except the claim for fraud—are subsumed by the Washington Products Liability Act; therefore, the Court **GRANTS** all Defendants' Motion to Dismiss these claims and dismisses these claims **WITH PREJUDICE**.

As to the Economic Loss Master Complaint claims arising under the laws of Washington: the Court finds that none of the claims are subsumed by the Washington Products Liability Act; therefore, the Court **DENIES** the Motion to Dismiss these claims.

As for negligence *per se*:

The Court finds that the Complaints sufficiently plead a cause of action against Manufacturer Defendants; however, the Court finds that the following jurisdictions do not recognize an independent cause of action for negligence *per se*: Arkansas; Arizona; California; Massachusetts; Maine; Nebraska; Rhode Island; and Texas. Therefore, the Court **GRANTS** the Motion to Dismiss the claims arising under the laws of these jurisdictions **WITH PREJUDICE**.

AS FOR NEGLIGENCE:

Against Manufacturer Defendants: the Court **DENIES** the Motion to Dismiss the negligence claims.

Against Wholesaler and Pharmacy Defendants: the Court **GRANTS** the Wholesaler and Pharmacy Defendants' Motion to Dismiss and dismisses these claims **WITHOUT PREJUDICE**.

Plaintiffs may make a motion for LEAVE TO AMEND all three Master Complaints as to the negligence claims according to the deadlines set in the accompanying Order.

AS FOR MEDICAL MONITORING:

Against all Defendants: the Court **GRANTS** the Motion to Dismiss to the extent the claims arise under the law of the following jurisdictions: Alabama; Arkansas; Connecticut; Georgia; Kentucky; Louisiana; Michigan; Mississippi; Nebraska; New Jersey; North Carolina; Oklahoma; South Carolina; Tennessee; Texas; Virginia; and Wisconsin.

Plaintiffs may make a motion for LEAVE TO AMEND the MMMC as to the medical monitoring claim according to the deadline set in the accompanying Order.

AS FOR STRICT LIABILITY:

Against Pharmacy Defendants: the Court **GRANTS** the Pharmacy Defendants' Motion to Dismiss, to the extent the claims arise under the law of the following jurisdictions: Alabama; Arizona; Arkansas; California; Connecticut; District of Columbia; Florida; Georgia; Hawaii; Illinois; Iowa; Louisiana; Maine; Maryland; Massachusetts; Michigan; Mississippi; New Hampshire; New Jersey; New Mexico; New York; North Carolina; Oklahoma; Pennsylvania; Tennessee; Utah; Virginia; Washington; and West Virginia.

Plaintiffs may make a motion for LEAVE TO AMEND as to the strict liability claim, according to the deadlines set in the accompanying Order.

Dated: 3 Feb 2021

/s/ Robert B. Kugler
ROBERT B. KUGLER
United States District Judge